Calculating Commercialization: 20 Years of NIDA SBIR Program

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Rationale and Objectives

The Small Business Innovation Research (SBIR) program is one of the largest sources of early-stage capital for small business concerns (SBC) in the US. At NIH, the SBIR program is primarily intended to encourage private sector commercialization of technology and to increase SBC participation in federally funded R&D. However, commercialization, as a program outcome, is difficult to measure due to a lack of established methodology and reliable data.

Objectives: (1) Establish metrics to measure commercialization of National Institute of Drug Addiction (NIDA) funded SBCs over period of 20 years (2) Identify factors associated with commercialization.

Materials and Methods

We conducted a retrospective analysis of a 100% sample (census) of 795 projects and 234 SBCs funded by the NIDA SBIR program from FY 1995 through July 2014. Commercialization data was obtained via extraction from unstructured Query-View-Report (QVR) project documentation and historical tracing. Commercialization metrics included both composite and individual indicators: (1) merger & acquisition (M&A), (2) stock offering (IPO), (3) private investments (PI), (4) product/services sales, (5) partnership or licensing (PL).

Analysis

1) The products of research of the NIDA-sponsored SBCs were classified into 6 product categories: health IT (n=88), therapeutics (n=67), research tools (n=44), medical devices (n=8), clinical research (n=9), education/training (n=18).

2) For SBIR program overall and for each product category we calculated cumulative transition rates (TR): from Phase I to II (TR2) and from Phase II to III (TR3).

3) We conducted logistic regression analysis to identify variables associated with transitions and calculated adjusted odds ratios (OR) and predicted probabilities (P) of TR3 (Adjusted rates).

Data Sources included Query-View-Report (QVR) System, NIH RePORTER, SBCs websites, and other public and private databases. Analysis was performed using SAS 9.4 for Windows.

Figure 1. Analytical Framework: SBIR Timeline, Key Questions and Outcomes

Q1 How many SBCs achieved Phase II Transition (T2)? 94/234 (40%)
Q2 What variables are associated with T2? Product, Finding by Multiple ICs
Outcome 1 Phase II Transition (**T2**):
SBC level: T2 Indicator
SBIR Level: **TR2** = 100* (N_{T2}/ N_{Total}) % SBC with Phase II or FT award

Q3 How many SBCs achieved Phase III Transition (T3)? A: 32 (14%) B: 57 (24%)
Q4 What variables are associated with T3? A: Product B: Product, T2
Outcome 2 Phase III Transition (**T3**):
SBC Level: T3 Indicator
SBIR Level: **TR3** = 100* (N_{T3}/ N_{Total}) Percent SBC achieved Commercialization:
A: Conservative = M&A or IPO or PI
B: Less Conservative = M&A or IPO or PI or Sales or PL

Figure 2. NIDA SBIR Portfolio: Less Conservative Commercialization Estimate.

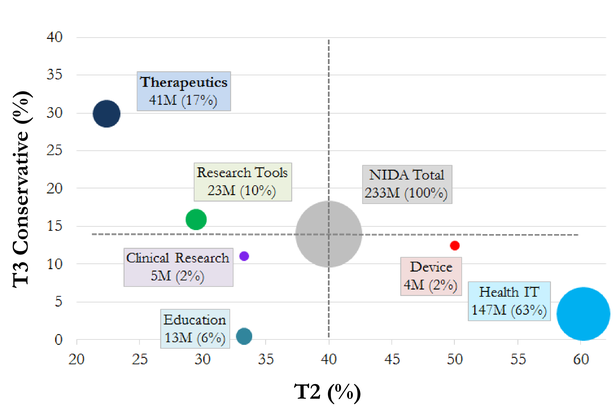

Figure illustrates overall SBIR and product-specific Phase II and III transition rates and SBIR funds received. Bubble diameter is proportional to SBIR funds; label shows product and funds received (% Total). Dash line shows NIDA average transition rates (TR). Horizontal line: Phase II TR (24%=57/234) Vertical: Phase III TR (40%=94/234)

Figure 3. NIDA SBIR Portfolio: Conservative Commercialization Estimate.

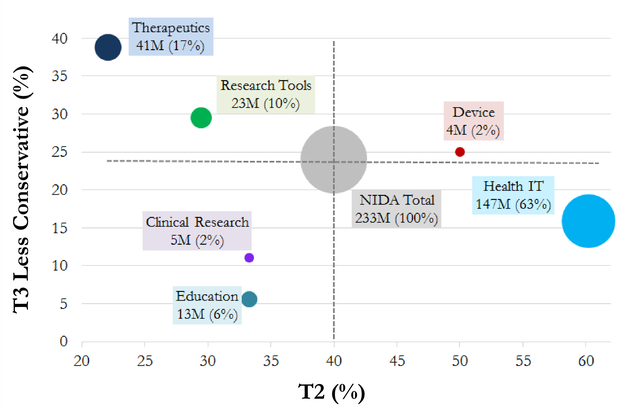

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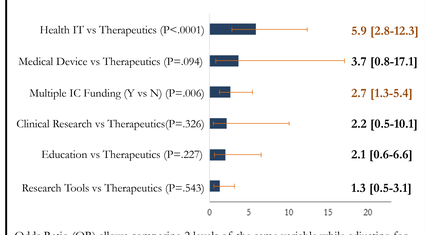
Figure 4. Odds Ratios (OR, 95%CI) of Phase II Transition by Product & Funding



Odds Ratio (OR) allows comparing 2 levels of the same variable while adjusting for other variables in the model. Adjusted Odds Ratios (OR) with 95% Confidence Intervals are shown as columns and horizontal lines. X-axis shows OR with 95% CI; Y-axis shows factors with two comparison levels and P-values for model significance.

Figure 5. Odds Ratios of Commercialization (LCE) by Product & Phase II Transition

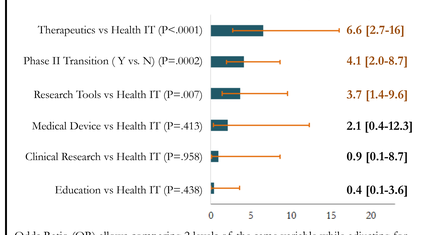


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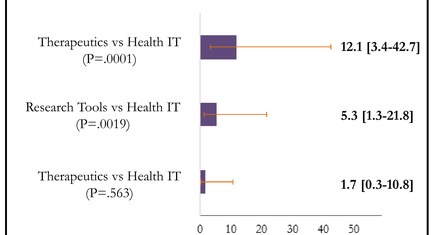
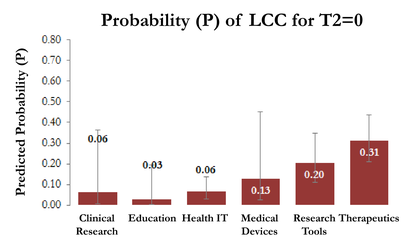
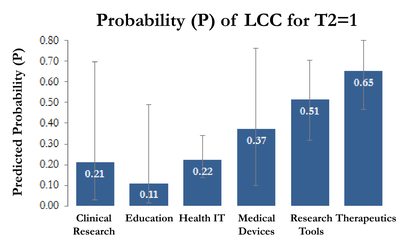
Figure 6. Odds Ratios of Commercialization (CE) by Product



Adjusted Odds Ratios (OR) with 95% Confidence Intervals are shown as columns and horizontal lines

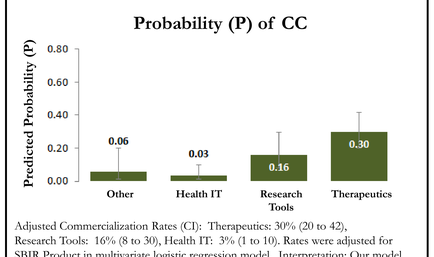
Figure 7. Probability (P) of Commercialization (LCE) by Product and Phase II Transition (T2=0 No Transition; T2=1 Transition)





Adjusted Commercialization Rates (CI): Therapeutics: 65% (47 to 80), Research Tools: 51% (32 to 71), Health IT: 22% (14 to 33). Rates were adjusted for Phase II Transition and SBIR Product in multivariate logistic regression model. Interpretation: Our model estimates that 65% of Therapeutics and 51% Research Tools SBCs with Phase II awards will achieve commercialization over a period of 20 years, compared with 22% of Health IT companies. The difference is statistically significant.

Figure 8. Probability (P) of Commercialization (CE) by Product



Adjusted Commercialization Rates (CI): Therapeutics: 30% (20 to 42), Research Tools: 16% (8 to 30), Health IT: 3% (1 to 10). Rates were adjusted for SBIR Product in multivariate logistic regression model. Interpretation: Our model estimates that 30% of Therapeutics and 16% Research Tools SBCs will achieve commercialization over a period of 20 years, compared with 3% of Health IT companies. The difference is statistically significant.

Results

I. Raw Data: NIDA SBIR Portfolio (1995-2014)

Portfolio was comprised of 795 projects from 234 SBCs, with total funding of $232,598,870 and median of $293,495. Overall SBIR program - T2 was 40%; T3 ranged from 14% (conservative estimate) to 24% (less conservative estimate). Transition rates varied by product, with therapeutics achieving significantly higher than average TR3 (conservative estimate: 30% (95%CI: 19-42) vs 14%, P=.0002; less conservative estimate: 39% (95%CI: 27-52) vs 24%, P=.0045) and Health IT achieving significantly higher TR2 (60% (95%CI: 49-70) vs 40%, P=.0001) (Figure 2, 3)

II. Modeling Results: Phase II Transition (T2)

The T2 rate was associated with SBIR product (χ^2=27.4, P<.0001) and funding by Multiple NIH Centers(χ^2=7.4, P=.006). Odds of T2 were higher for Health IT companies (OR=5.9; 95% CI:2.8-12.3), compared with Therapeutics; and for SBCs funded by multiple NIH Centers (OR=2.7; 95% CI:1.3-5.4), compared with funded by NIDA only (Figure 4)

III. Modeling Results: Phase III Transition (T3)

A. Conservative estimate: The T3 rate was associated with product (χ^2=19.1, P<.001). Odds of CC were higher for Therapeutics (OR=12.1; 95% CI:3.4-42.7) and Research Tools (OR=5.3; 95% CI:1.3-21.8), compared with Health IT (Figure 6). Adjusted Rates were 30% for Therapeutics, 16% for Research Tools and 3% for Health IT. (Figure 8)

B. Less Conservative Estimate: The T3 rate was associated with the product (χ^2=21.4, P<.001) and Phase II Transition (χ^2=14.3, P<.001). Odds of LCC were higher for Therapeutics (OR=6.6; 95% CI:2.7-16) and Research Tools (OR=3.7; 95% CI:1.4-9.6), compared with Health IT companies; and for SBCs with Phase II Transition (OR=4.1; 95% CI: 2.0-8.7), compared with no Phase II Transition (Figure 5). Adjusted Rates were higher for Therapeutics (65%, 47 to 80) and Research Tools (51%, 32 to 71), compared with Health IT (22%, 14 to 33). (Figure 7).

Conclusion

1. NIDA SBIR commercialization ranged from 14% (conservative estimate) to 24% (less conservative estimate).
2. SBIR Product was the most important factor associated with both Ph II and Ph III Transitions.
3. Therapeutics and Research Tools were more likely to achieve Phase III Transition (commercialization), compared with Health IT.
4. Our analysis supports the notion of the difficulties in the commercialization of Health IT and suggests a necessity of additional programmatic attention to those grants during both Ph I and Ph II.

Limitations

1. Data quality and availability: databases, self reported
2. Study design: census vs "vintage" year study
3. Precision: A larger study is needed to obtain more precise estimates (narrower confidence intervals).

References

1. Interagency Advisory Committee on SBIR Metrics, 2015;
2. An Assessment of the SBIR Program at the NIH. National Academies, 2009
3. Hosmer D., Lemeshow S. Applied Logistic Regression, 3rd Edition, 2013